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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,403	04/15/2002	Donald Gullberg	000510-010	3147

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EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,403	GULLBERG, DONALD	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-149 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed on 12/3/01, is acknowledged.
2. Claims 1-149 are pending.
3. It is noted that SEQ ID NO:1 is a nucleic acid molecule which is limited to its nucleic acid components. For the examination purposes, claims that recite "the amino acid sequence shown in SEQ ID NO:1" are considered to read as "the amino acid sequence encoded by SEQ ID NO:1".
4. Claims 5 and 17, recite a process of providing, for the Examination purposes, the claims are interpreted as a method of producing.

Election/Restrictions

5. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
6. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.
 - I. Claims 1, 11, 13-14, 20, 22-25, 28, 94, 106, 113, 115-116, 119, 121-124, 126, 146 and 149, drawn to a recombinant or isolated integrin subunit $\alpha 11$ having the amino acid sequence encoded by SEQ ID NO: 1, and homologues and fragments thereof and a vaccine.
 - II. Claims 2-10, 15-19, 26-27, 94, 107-112, 117-118, 125, drawn to an isolated polynucleotide or oligonucleotide comprising nucleotide coding for an integrin subunit $\alpha 11$ or for homologues or fragments thereof, wherein the polynucleotide having SEQ ID NO:1, vectors, host cells, and methods of producing the polypeptide and a vaccine.
 - III. Claims 12, 21, 29, 91-93, 114, 120, 127, 144-145, drawn to a binding entities having the capability of binding specifically to integrin subunit $\alpha 11$, or to homologues or fragments thereof, which entity is proteins and a composition thereof.
 - IV. Claims 12, 21, 29, 91-93, 114, 120, 127, 144-145, drawn to a binding entities having the capability of binding specifically to integrin subunit $\alpha 11$, or to homologues or fragments thereof, which entity is peptides and a composition thereof.

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- V. Claims 12, 21, 29, 91-93, 114, 120, 127, 144-145, drawn to a binding entities having the capability of binding specifically to integrin subunit $\alpha 11$, or to homologues or fragments thereof, which entity is carbohydrates and a composition thereof.
- VI. Claims 12, 21, 29, 91-93, 114, 120, 127, 144-145, drawn to a binding entities having the capability of binding specifically to integrin subunit $\alpha 11$, or to homologues or fragments thereof, which entity is lipids and a composition thereof.
- VII. Claims 12, 21, 29, 91-93, 114, 120, 127, 144-145, drawn to a binding entities having the capability of binding specifically to integrin subunit $\alpha 11$, or to homologues or fragments thereof, which entity is natural integrin binding ligands and a composition thereof.
- VIII. Claims 12, 21, 29, 91-93, 114, 120, 127, 144-145, drawn to a binding entities having the capability of binding specifically to integrin subunit $\alpha 11$, or to homologues or fragments thereof, which entity is antibodies and a composition thereof.
- IX. Claims 32, 41 and 129-138, drawn to a process for determining the differentiation-state of cells during differentiation using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- X. Claims 32, 36, 41 and 129-138, drawn to a process for determining the differentiation-state of cells during development using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- XI. Claims 32-35, 41 and 129-138, drawn to a process for determining the differentiation-state of cells in pathological conditions using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- XII. Claims 32, 41 and 129-138, drawn to a process for determining the differentiation-state of cells in tissue regeneration using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- XIII. Claims 32, 39, 41 and 129-138, drawn to a process for determining the differentiation-state of cells in transplantation using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- XIV. Claims 32, 37, 41 and 129-138, drawn to a process for determining the differentiation-state of cells in therapeutic and physiological reparation of tissues using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.

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- XV. Claims 38, 41, drawn to a process for selection and analysis, or sorting, isolating or purification of chondrocytes and/or muscle cells using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- XVI. Claims 32, 42 and 129-138, drawn to a process for determining the differentiation-state of cells during differentiation using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in situ*.
- XVII. Claims 32, 36, 42 and 129-138, drawn to a process for determining the differentiation-state of cells during development using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in situ*.
- XVIII. Claims 32-35, 42 and 129-138, drawn to a process for determining the differentiation-state of cells in pathological conditions using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in situ*.
- XIX. Claims 32, 42 and 129-138, drawn to a process for determining the differentiation-state of cells in tissue regeneration using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in situ*.
- XX. Claims 32, 39, 42 and 129-138, drawn to a process for determining the differentiation-state of cells in transplantation using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in situ*.
- XXI. Claims 32, 37, 42 and 129-138, drawn to a process for determining the differentiation-state of cells in therapeutic and physiological repair of tissues using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXII. Claims 38, 42, drawn to a process for selection and analysis, or sorting, isolating or purification of chondrocytes and/or muscle cells using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXIII. Claims 32, 43 and 129-138, drawn to a process for determining the differentiation-state of cells during differentiation using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXIV. Claims 32, 36, 43 and 129-138, drawn to a process for determining the differentiation-state of cells during development using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXV. Claims 32-35, 43 and 129-138, drawn to a process for determining the differentiation-state of cells in pathological conditions using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.

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- XXVI. Claims 32, 43 and 129-138, drawn to a process for determining the differentiation-state of cells in tissue regeneration using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXVII. Claims 32, 39, 43 and 129-138, drawn to a process for determining the differentiation-state of cells in transplantation using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXVIII. Claims 32, 37, 43 and 129-138, drawn to a process for determining the differentiation-state of cells in therapeutic and physiological reparation of tissues using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vitro*.
- XXIX. Claims 38, 43, drawn to a process for selection and analysis, or sorting, isolating or purification of chondrocytes and/or muscle cells using an integrin subunit $\alpha 11$ encoded by SEQ ID NO:1 *in vivo*.
- XXX. Claims 52, 61 and 62, drawn to a process for determining the differentiation-state of cells during differentiation using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vitro*.
- XXXI. Claims 52, 57 and 62, drawn to a process for determining the differentiation-state of cells during development using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vitro*.
- XXXII. Claims 52-56 and 62, drawn to a process for determining the differentiation-state of cells in pathological conditions using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vitro*.
- XXXIII. Claims 52 and 62, drawn to a process for determining the differentiation-state of cells in tissue regeneration using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vitro*.
- XXXIV. Claims 52, 60 and 62, drawn to a process for determining the differentiation-state of cells in transplantation using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vitro*.
- XXXV. Claims 52, 58 and 62, a process for determining the differentiation-state of cells in therapeutic and physiological repair of tissues using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vitro*.
- XXXVI. Claims 59 and 62, drawn to a process for selection and analysis, or for sorting, isolating or purification of chondrocytes and/or muscle cells *in vitro*.

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- XXXVII. Claims 52, 61 and 63, drawn to a process for determining the differentiation-state of cells during differentiation using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in situ*.
- XXXVIII. Claims 52, 57 and 63, drawn to a process for determining the differentiation-state of cells during development using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in situ*.
- XXXIX. Claims 52-56 and 63, drawn to a process for determining the differentiation-state of cells in pathological conditions using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in situ*.
- XL. Claims 52 and 63, drawn to a process for determining the differentiation-state of cells in tissue regeneration using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in situ*.
- XLI. Claims 52, 60 and 63, drawn to a process for determining the differentiation-state of cells in transplantation using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in situ*.
- XLII. Claims 52, 58 and 63, a process for determining the differentiation-state of cells in therapeutic and physiological repair of tissues using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in situ*.
- XLIII. Claims 59 and 63, drawn to a process for selection and analysis, or for sorting, isolating or purification of chondrocytes and/or muscle cells *in situ*.
- XLIV. Claims 52, 61 and 64, drawn to a process for determining the differentiation-state of cells during differentiation using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vivo*.
- XLV. Claims 52, 57 and 64, drawn to a process for determining the differentiation-state of cells during development using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vivo*.
- XLVI. Claims 52-56 and 64, drawn to a process for determining the differentiation-state of cells in pathological conditions using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vivo*.
- XLVII. Claims 52 and 64, drawn to a process for determining the differentiation-state of cells in tissue regeneration using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vivo*.

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- XLVIII. Claims 52, 60 and 64, drawn to a process for determining the differentiation-state of cells in transplantation using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vivo*.
- XLIX. Claims 52, 58 and 64, a process for determining the differentiation-state of cells in therapeutic and physiological repair of tissues using binding entities having the capability of binding specifically to binding sites of an integrin subunit $\alpha 11$ *in vivo*.
- L. Claims 59 and 64, drawn to a process for selection and analysis, or for sorting, isolating or purification of chondrocytes and/or muscle cells *in vivo*.
- LI. Claims 72, 81 and 82, drawn to a process for determining the differentiation-state of cell during differentiation using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vitro*.
- LII. Claims 72, 77 and 82, drawn to a process for determining the differentiation-state of cell during development using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vitro*.
- LIII. Claims 72-76 and 82, drawn to a process for determining the differentiation-state of cell in pathological conditions using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vitro*.
- LIV. Claims 72 and 82, drawn to a process for determining the differentiation-state of cell in tissue regeneration using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vitro*.
- LV. Claims 72, 80 and 82, drawn to a process for determining the differentiation-state of cell in transplantation using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vitro*.
- LVI. Claims 72, 78 and 82, drawn to a process for determining the differentiation-state of cell in therapeutic and physiological reparation of tissues using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vitro*.
- LVII. Claims 79 and 82, drawn to a process for selection and analysis, or for sorting, isolating or purification of chondrocytes and/or muscle cells *in vitro*.

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- LVIII. Claims 72, 81 and 83, drawn to a process for determining the differentiation-state of cell during differentiation using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in situ*.
- LIX. Claims 72, 77 and 83, drawn to a process for determining the differentiation-state of cell during development using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in situ*.
- LX. Claims 72-76 and 83, drawn to a process for determining the differentiation-state of cell in pathological conditions using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in situ*.
- LXI. Claims 72 and 83, drawn to a process for determining the differentiation-state of cell in tissue regeneration using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in situ*.
- LXII. Claims 72, 80 and 83, drawn to a process for determining the differentiation-state of cell in transplantation using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in situ*.
- LXIII. Claims 72, 78 and 83, drawn to a process for determining the differentiation-state of cell in therapeutic and physiological reparation of tissues using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in situ*.
- LXIV. Claims 79 and 83, drawn to a process for selection and analysis, or for sorting, isolating or purification of chondrocytes and/or muscle cells *in situ*.
- LXV. Claims 72, 81 and 84, drawn to a process for determining the differentiation-state of cell during differentiation using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vivo*.
- LXVI. Claims 72, 77 and 84, drawn to a process for determining the differentiation-state of cell during development using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vivo*.

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- LXVII. Claims 72-76 and 84, drawn to a process for determining the differentiation-state of cell in pathological conditions using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vivo*.
- LXVIII. Claims 72 and 84, drawn to a process for determining the differentiation-state of cell in tissue regeneration using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vivo*.
- LXIX. Claims 72, 80 and 84, drawn to a process for determining the differentiation-state of cell in transplantation using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vivo*.
- LXX. Claims 72, 78 and 84, drawn to a process for determining the differentiation-state of cell in therapeutic and physiological reparation of tissues using a polynucleotide or oligonucleotide of SEQ ID NO:1 that fails to hybridize to a polynucleotide or oligonucleotide encoding an integrin subunit $\alpha 10$ *in vivo*.
- LXXI. Claims 79 and 84, drawn to a process for selection and analysis, or for sorting, isolating or purification of chondrocytes and/or muscle cells *in vivo*.
- LXXII. Claims 95 and 147, a method of therapy, whereby vector comprising a polynucleotide or oligonucleotide coding for a subunit $\alpha 11$ of SEQ ID NO:1.
- LXXIII. Claim 96, a method of promoting adhesion of cells comprising introducing to a cell sample binding entities having the capability of binding specifically to binding sites of a integrin subunit $\alpha 11$ encoded by SEQ ID NO:1.
- LXXIV. Claims 97 and 104, drawn to a method of targeting for antiadhesive drugs or molecules in tissues comprising adding to a tissue an integrin heterodimer comprising an integrin subunit $\alpha 11$ and a subunit β , or subunit $\alpha 11$.
- LXXV. Claim 98, drawn to a method of *in vitro* detecting the presence of integrin binding entities comprising introducing $\alpha 11$ subunit thereby causing $\alpha 11$ subunit to modulate the binding to its natural ligand or other integrin binding proteins.
- LXXVI. Claim 103, drawn to a method of promoting adhesion of chondrocytes and/or osteoblasts to surfaces of implants to stimulate osseointegration comprising introducing binding entities having the capability of binding specifically to an integrin subunit $\alpha 11$ of SEQ ID NO: 2 or a heterodimer thereof.

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LXXVII. Claims 105 and 148, drawn to a method of stimulating the formation of cartilage or bone with a pharmaceutical agent or an antibody with is capable of targeting an integrin heterodimer comprising $\alpha 11$ subunit.

LXXVIII. Claim 105 and 148, drawn to a method of inhibiting or blocking the formation of cartilage or bone with a pharmaceutical agent or an antibody with is capable of targeting an integrin heterodimer comprising $\alpha 11$ subunit.

Claims 30, 128 and 44-49 are linking claims and will be examined along with any elected groups of IX-XXIX.

Claims 50-51 and 65-70 are linking claims and will be examined along with any elected groups of XXX-L.

Claims 71, 85-90, 101-102 and 139-143 are linking claims and will be examined along with any elected groups of LI-LXX.

8. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Goetinck et al (U.S Pat. No. 5,686,059) (see entire document).

The '059 patent teaches a CBS1 motif included in the rat VLA-1 integrin molecule consisting of DIVIVLDGS fragment (referenced SEQ ID NO: 34, in particular) that corresponds to amino acid residues 164-172 of claimed amino acid sequence encoded by SEQ ID NO: 1 (see col. 4, lines 10-11 in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

9. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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- A. If Group XI, XVIII, XXV, XXXII, XXXIX, XLVI, LIII, LX or LXVIII is elected, applicant is required to elect a process for determining the differentiation-state of cells or development in a pathological conditions wherein the pathological condition is:
- a. damage of muscles,
 - b. muscle dystrophy,
 - c. fibrosis,
 - d. wound healing,
 - e. damage of cartilage,
 - f. damage of bone,
 - g. damage of both cartilage and bone,
 - h. cartilage diseases,
 - i. bone diseases,
 - j. cartilage and bone disease,
 - k. trauma,
 - l. rheumatoid arthritis,
 - m. osteoarthritis, or
 - n. osteoporosis.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

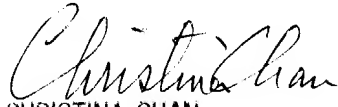
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11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
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July 12, 2004


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